DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

5189

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 2953802

February 15, 2001

Kenneth J. Kimes and Sandra J. Ward, Co-Owners
Greensward Nurseries
1255 Hames Road
Aptos, CA 95003

WARNING LETTER

Dear Mr. Kimes and Ms. Ward:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 1255 Hames Road, Aptos, CA on July 17, 2000 and September 20-21, 2000.

The inspection revealed that you have failed to adopt effective preventive controls to reduce the risk of raw sprouts serving as a vehicle for foodborne illness and to assure that sprouts are not adulterated under the food safety provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You do not have an adequate microbial testing program for your soil-grown sprouts, namely buckwheat, sunflower, wheat grass, and pea shoots. Although you refer to these products as "micro greens," FDA considers these soil-grown products to be sprouts, as they were specifically identified in the evaluations and recommendations on sprouted seeds by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). You may refer to the NACMCF sprout document at the following internet address: http://vm.cfsan.fda.gov/~mow/sprouts2.html. We recommend that your labels for organic pea shoots and organic wheat grass bear the statement "SEEDS AND SPROUTS ORGANICALLY GROWN," identifying these products as "sprouts."

Specifically, your sprouts are adulterated within the meaning of section 402(a)(4) of the Act because they have been prepared under insanitary conditions whereby they may have been rendered injurious to health. The conditions under which the sprouts are produced are considered insanitary since (1) effective preventive controls, particularly microbial testing of each lot of product, have not been adopted and implemented by your sprouting facility; and (2) the well water that is used in your sprout processing operation is not of adequate sanitary quality. Your firm is not testing the well water monthly, and when laboratory test results indicated that the well water was positive for coliforms in May and

June 2000, you took corrective action by adding [redacted] to the water, but failed to verify the effectiveness of the action taken.

Since your products meet the definition of sprouts, they are subject to the recommendations outlined in the guidance documents, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production" and "Reducing Microbial Food Safety Hazards For Sprouted Seeds," both of which are enclosed for your information. Please note that in the latter document, under "Seed Treatment," it is recommended that "Seeds for sprouting should be treated with one or more treatments (such as 20,000 ppm calcium hypochlorite) that have been approved for reduction of pathogens in seeds or sprouts. Some treatments can be applied at the sprouting facility while others will have to be applied earlier in the seed production process. However, at least one approved antimicrobial treatment should be applied immediately before sprouting." Antimicrobials are either pesticide chemicals or food additives, depending on where they are used. As such their use on seeds for sprouting must be approved by the Environmental Protection Agency (EPA) or FDA. To find out what antimicrobials have been approved by EPA or FDA for use on seeds for sprouting, you may call 202-418-3098. You do not necessarily have to use the 20,000 ppm calcium hypochlorite seed treatment.

We are also concerned that the sprout growing soil prepared on-site is composted waste from your sprouts mixed with sawdust. Current guidance for soil-grown sprouts recommends the use of sterilized growing soil for use with soil-grown sprouts to reduce the possibility of contamination with pathogenic bacteria from the growing media. Further guidance can be found in the video for safer processing of sprouts. The order form for this video is available at http://vm.cfsan.fda.gov/~dms/sprouvid.html.

At the conclusion of the inspection, the insanitary practices were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction. FDA will consider enforcement actions against any party who does not have effective preventive controls in place with respect to sprouts, in particular, effective microbial testing.

Please advise FDA in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District

Enclosures:

Guidance for Industry Document, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production"

Guidance for Industry Document, "Reducing Microbial Food Safety Hazards For Sprouted Seeds"

Form FDA 483